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510(k) Summary
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5-Aug-09

AUG 07 2009

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Official Contact: Ross Deardorff - President

Proprietary or Trade Name: Wound Cleanser

Common/Usual Name: Wound cleanser

Classification Name/Code: FRO – Dressing, wound, drug
CFR – unclassified – pre-amendment

Device: Wound Cleanser

Predicate Devices: Oculus – Dermacyn – K042729
Anacapa – Anasept Skin and Wound Cleanser – K073547

Device Description:
The Wound Cleanser is an aqueous solution of sodium hypochlorite, modified with sodium bicarbonate, used as a solution to mechanically cleanse and debride open wounds. The sodium hypochlorite concentration 0.0125% weight / volume.

Sodium hypochlorite is a solution preservative.

Indications for Use:
OTC: Wound Cleanser is intended for mechanical cleansing of dirt and debris from skin, abrasions, cuts, and minor irritations.

Professional Use: Wound Cleanser for mechanical cleansing and debriding acute and chronic wounds; such as stage I-IV pressure ulcers, diabetic foot ulcers, pre and post surgical wounds, first and second degree burns, grafted and donor sites.

Patient Population: Patients with acute or chronic wounds.

Environment of Use: Hospitals, nursing homes, wound clinics and pre and post hospitals

Summary of substantial equivalence

	Predicate **Oculus – Dermacyn** **K042729**	**Predicate** **Anacapa - Anasept** **K073547**	**Proposed** **Wound Cleanser**
Indications for Use	Intended for moistening and debriding acute and chronic dermal lesions, such as pressure ulcers, statis ulcers, diabetic ulcers, post-surgical wounds, first and second degree burns, abrasions and minor irritations of the skin	**OTC:** Intended for OTC use for mechanical cleansing of dirt and debris from skin abrasions, minor irritations, cuts, exit sites and intact skin **Professional Use:** Intended for professional use for cleansing and removal of foreign materials including micro-organisms and debris from wounds such as Stage I-IV pressure ulcers, diabetic foot ulcers, port-surgical wounds, first and second degree burns, grafted and donor sites.	**OTC:** Wound Cleanser is intended for mechanical cleansing of dirt and debris from skin, abrasions, cuts, and minor irritations. **Professional Use:** Wound Cleanser for mechanical cleansing and debriding acute and chronic wounds; such as stage I-IV pressure ulcers, diabetic foot ulcers, pre and post surgical wounds, first and second degree burns, grafted and donor sites.
OTC Prescriptive	Prescriptive	OTC Prescriptive (Professional use)	OTC Prescriptive (Professional use)
Environments of use	Not specified	Hospitals, nursing homes, wound clinics and pre and post hospitals	Hospitals, nursing homes, wound clinics and pre and post hospitals

	Predicate **Oculus – Dermacyn** **K042729**	**Predicate** **Anacapa - Anasept** **K073547**	**Proposed** **Wound Cleanser**
Features and Performance Characteristics			
Ingredients	Purified Water 99.97%, chloride <200 ppm, chlorate <20ppm, hypochlorous acid hypochlorite < 85 ppm. Results in very low concentration of hypochlorous acid and hypochlorite (85 ppm or 0.0085%)	Isotonic solution Sodium Hypochlorite	Purified Water Sodium bicarbonate Sodium Hydroxide Sodium Hypochlorite concentration: 0.0125% Weight / volume
Non-clinical Performance Biocompatibility Stability Shelf-life	Tested as stated in 510(k) Summary	Tested as stated in 510(k) Summary	Cytotoxicity Sensitization Dermal Irritation Shelf-life – 2 years Time-to-use - 3 months
Contraindications and Warnings	None	None	***Warnings*:** ▪ **For external use only** ▪ **Not for injection** ▪ **Not for use in or near the eyes** ▪ **Stop use and ask a doctor if** redness, irritation, swelling or pain persists or increases. ▪ **Do not use if** sensitive to any of the compounds ▪ Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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The Wound Cleanser is viewed as substantially equivalent to the predicate devices because:

Indications –

- Identical to predicate – Oculus – Dermacyn – K042729
- OTC and Professional Use – identical to Anacapa Anasept cleanser – K073547

Formulation / Technology –

- Similar formulation / technology used – Oculus – Dermacyn – K042729 and Anacapa Anasept cleanser – K073547

Materials –

- The materials in patient contact are identical to predicate device, Oculus – Dermacyn – K042729

Environment of Use –

- Identical to predicate – Anacapa Anasept cleanser – K073547

Differences –

The differences are:

- Concentration 0.0125% weight to volume of sodium hypochlorite

Any other differences are not significant between the proposed device and the predicate device and do not introduce any new patient safety issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Century Pharmaceuticals, Inc.
% ProMedic, Inc.
Mr. Paul Dryden
24301 Woodsage Drive
Banita Springs, Florida 34134

AUG 07 2009

Re: K090791
Trade/Device Name: Wound Cleanser
Product Code: FRO
Dated: July 30, 2009
Received: August 4, 2009

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090791

Indications for Use Statement

510(k) Number: K090791

Device Name: Wound Cleanser

Indications for Use:

OTC: Wound Cleanser is intended for mechanical cleansing of dirt and debris from skin, abrasions, cuts, and minor irritations.

Professional Use: Wound Cleanser intended for mechanical cleansing and debriding acute and chronic wounds; such as stage I-IV pressure ulcers, diabetic foot ulcers, pre and post surgical wounds, first and second degree burns, grafted and donor sites.

The sodium hypochlorite concentration of 0.0125% weight / volume.

Prescription Use XX (Part 21 CFR 801 Subpart D)	**or**	**Over-the-counter use XX** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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